

## REMARKS

### Formalities

We note that in line 9 of the office action summary, the specification has been objected to by the examiner but no comments were made. In the previous amendment, amendments to the abstract, drawings and specification were made but were not acknowledged by the examiner in this office action. Withdrawal of the objection is earnestly requested.

### Interview

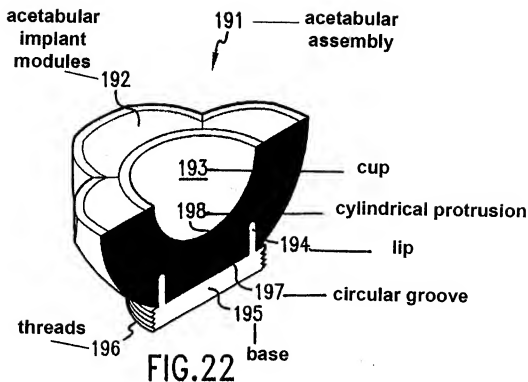
Applicant thanks Examiner for the Office Action mailed August 11, 2005 and for the brief interview granted. The telephone interview with Examiner Blanco on December 9, 2005 discussed the meaning of segmented shells. Specifically, it was agreed that segmented shells have separate pieces which form a shell, such that the separate pieces may be inserted through a tube into the body and assembled into a shell. This definition is clearly disclosed in the specification. For example, page 4, first partial paragraph recites the "segmented shell comprises plurality of separate parts which may be inserted through a hole in the femur of the patient and assembled and attached to the hip bone to form a cup shaped first shell." During the interview, the Examiner concurred with Applicant's definition of a segmented shell.

### Response

Based on the consensus reached on the term segmented shell, the Applicant believes that the response to arguments in paragraph 6 and 7 of the Office Action are hereby traversed. Specifically, De Carlo, Jr. '467 does not disclose any segmented shell, as that term is used in the present application. Thus, the Examiner's reference to body portion 64 of DeCarlo, Jr. '467 as a segmented shell is an overly broad construction of that term. The reference shows only a one piece shell. Also, the retaining ring portion 74 is not a second segmented shell. Indeed, a person of ordinary skill in the art would not consider the retaining ring portion 74 as a shell at all. Instead, its sole function is to work with body portion 64 to retain the socket bearing 12 in body portion 64. It does not perform the same function as a second shell which provides a load bearing surface that supports and retains the cup for use with a small support ball 110, as disclosed on page 24, ll 6-12 of the specification. Thus, a person of ordinary skill in the art would not consider the retaining ring to be a second shell.

Now referring to paragraph 3 of the Office Action, Claims 1 and 8 have been amended to correct the typographical error objected to in part A of paragraph 3. Claim 11 has been amended to delete "said shaft further comprising."

Now referring to paragraph 5 of the Office Action, as previously discussed, DeCarlo, Jr. (U.S. 4,524,467) fails to disclose, teach or suggest a segmented shell. Also, DeCarlo, Jr. '467 fails to disclose, teach or suggest a second shell, as that term is known in the art, because the retaining ring portion 74 does not perform the same function as a second shell, which is needed to support and retain a cup when a small ball is used due to the size of a patient's bone. Since DeCarlo, Jr. '467 fails to disclose, teach or suggest a segmented shell; therefore, the reference fails to establish *prima facie* anticipation or obviousness of claims 1 and 5, which recited a segmented shell and a second shell.



Now referring to paragraph 7 of the office action, claims 1, 5, and 8, are not anticipated by the cited reference. In order to anticipate a claim, a reference must disclose each and every element of a claim exactly.

Hyde fails to disclose a second shell, as that term is defined in the art and the specification. Now referring to claim 2, Hyde also fails to disclose segments "pivotally engaging said base." Now referring to claim 8, Hyde also fails to disclose "a second shell... comprises: a ...a plurality of parts" and .."each of said plurality of parts being linked to one another." Thus, claims 1, 2, 5, and 8 are not anticipated by Hyde. Furthermore claims 1, 2, 5, and 8 are nonobvious over Hyde for the following reasons. First, Hyde describes only 1 shell and 1 cup, which is referenced to by Hyde as the acetabular assembly 191. As shown in Figure

22 of Hyde, depicted above with color for emphasis of clarity, only one shell is present. There may be some sort of coating applied to the outer portion of each implant module 192, but this coating is a portion of the implant modules and is not, otherwise, labeled or identified. Such a coating is known in the art and is not considered a second shell and is not within the first shell.

The acetabular assembly 191 comprises acetabular implant modules 192, (one module shaded for emphasis of clarity) which are inserted and secured on lip 194 of base 195, and cup 193, " which is positioned in front of implant modules 194 [sic 192]...thereby assembling acetabular assembly 191 in situ. (Col. 21, ll 8-23). Threads 196 are provided on a base 195 of the acetabular assembly 191. (Col. 21, ll 13-14). Furthermore, the specification does not enable the assembly of a second shell, because the lip 194 and a portion of the cup 193, which is referred to a protrusion 198, is responsible for locking the implant modules by "interference or pressure fit." (Col. 21, ll. 19-22). Thus, the reference to 194 and 196 cannot be used to suggest a segmented shell or a second segmented shell as well. As a result, Hyde fails to disclose, teach or suggest any second shell, as that term is defined in the specification of the present application. Hence claims 1, 2, 6 and 8 are not anticipated nor rendered obvious by Hyde.

Claims 2 and 8 have additional limitations that are also not disclosed, taught, or suggested by Hyde.

Claims depending from claim 8 includes all of the limitations of claim 8 and additional limitations. Therefore, these dependent claims are not anticipated by the reference.

With respect to the rejections of claims 1, 2, and 5 under 35 U.S.C. §102 in paragraph 9 by Afriat, Afriat does not teach a segmented shell as that term is defined in the specification. As clearly shown in Figure 2B and described in Col 5, lns. 42-45 of Afriat, US 6,811,569, the acetabular cup 2 has expansion slots 6 which are uniformly and symmetrically distributed over its periphery. The slots are formed in the direction of the pole  $P_2$  of the acetabular cup in such a way to form a segment 7 between each slot but the segments are integrally joined and not separate pieces. They are not "separate parts which may be inserted through a hole in the femur of the patient and assembled and attached to the hip bone to form a cup shaped shell." Additionally, the intermediate element 3, does not have a "plurality of parts, each part, of said plurality of parts, having a longitudinal axis, a first longitudinal end, a second longitudinal end, a first face and a second face, a pair of sides, opposing one another across said longitudinal

axis, ... one of said plurality of parts, said plurality of parts form said second shell so that said second shell is cup-shaped," as recited in claim 8. The intermediate element 3 screws into the acetabular cup 2, causing the segments to flex outward, gripping the bone.

In addition, Afriat teaches away from other art because Afriat's concept runs counter to the teaching of most of the prosthesis patents to date, which strive for a minimum of elasticity between the different components. (Col 4, lns. 1-9.) Thus, Afriat cannot be combined with Hyde, for example, because Afriat teaches away from Hyde. Thus, claims 1, 2, 8, and 12 are neither anticipated nor obvious over Afriat as there is no motivation to combine Afriat's teachings with Hyde's teachings. All claims depending from claim 1 are amended to depend from claim 2.

Claim 2 includes all of the limitations of claim 1 and additional limitations. Therefore, claim 2 is not anticipated nor rendered obvious by Afriat. Specifically, the segments in Afriat do not teach or suggest the geometry of the separate segments of claim 2.

Claims 3 and 4 include all of the limitations of claim 2 and additional limitations. Hence, claims 3, 4 are nonobvious over the references cited by the Examiner.

Claims 5, 7 are amended to depend upon claim 2 and have additional limitations. Hence, they are not anticipated nor rendered obvious by any of the references.

FIG. 29

Grimes

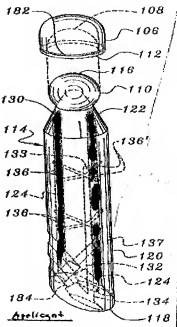
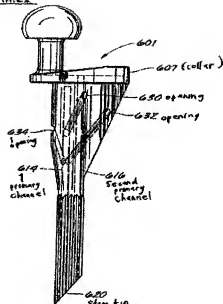


FIG. 12

Now referring to paragraph 11, *prima facie* obviousness does not exist. In order to establish *prima facie* obviousness over the claims of the invention, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest every limitation of the invention.

First, Hyde clearly failed to disclose, teach or suggest any second shell, as the reference only disclosed one shell and a cup. The combination of Hyde and Grimes do not teach or suggest the limitations of claims 10, 11. As clearly shown in Figures 29 (figure depicted), 30, Grimes does not teach at "least one channel passing through said body of said shaft such that said at least one channel extends from said second end of said shaft through said body to an area external to said neck and adjacent to said neck." By contrast, Figure 12 of the applicant's

patent application clearly shows one example of a channel extending to an area external to the neck and adjacent to the neck. (Figure provided shows the shaded channels.) The specification, pg. 16, first paragraph, states that the shaft 114 is cannulated, having at least one tube 124 that extends from an open first end 126 at the bottom 128 of the shaft 114 to an open second end 130 at the neck 122. Thus, this example shows the clear difference between the channels shown in the reference and the language of the claims.

Thus, the combination of Hyde and Grimes fail to establish *prima facie* obviousness because neither reference, alone or combined, teaches or suggests each and every element of the claims. Additionally, claim 10 is amended to depend upon claim 8. As discussed earlier, claim 8 is not anticipated nor rendered obvious by Hyde. Thus, claim 10 is not anticipated nor is rendered obvious by any of the references.

Claim 11 includes all of the limitations of claims 1 and 10 and additional limitations. Therefore, claim 11 is not anticipated nor rendered obvious by Grimes.

Claim 9 depends on claim 8 and has additional limitations. Hence, the claim is not anticipated nor rendered obvious by Afriat. As stated by the examiner, claim 9 stands allowable if rewritten to include the limitations of the base claim and any intervening claims.

Claim 12 is amended to incorporate the limitations of claim 1 and additional limitations. As stated by the examiner, claim 12 stands allowable if rewritten to include the limitations of the base claim and any intervening claims. Therefore, claim 12 is not anticipated nor rendered obvious by any of the references.

The amendments to the claims now put the application in condition for allowance. The Applicant respectfully requests that the Examiner enter the amendments and indicate allowance of the claims that are now pending in this application.

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Inventor(s): Tarabishy

Atty: CJP/kat

Title: "Joint Prosthesis"

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